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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,259	10/28/2003	Jeffrey Browning	A041 CON	7052

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EXAMINER	
ANGELL, JON E	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 11/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/696,259	BROWNING, J.	
	Examiner	Art Unit	
	Jon Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Action is in response to the communication filed on 8/23/2006.

The amendment filed 8/23/2006 is acknowledged and has been entered.

Claims 1-7 are currently pending in the application and are examined herein.

Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Claim Rejections - 35 USC §§ 101 and 112, 1st paragraph

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-7 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial and specific asserted utility or, alternatively, a well established utility.

The instant claims are drawn to DNA molecules which encode BMOG polypeptides. It is noted that the utility of the claimed vector, host cell and method of making the polypeptide all rely on the utility of the DNA and the encoded polypeptide (BMOG).

The specification discloses that BMOG or variants thereof are expressed by germinal center B cells, and *may* have immunoregulatory functions or *may* be used to regulate the immune system in autoimmune or inflammatory disease (emphasis added, see Summary of the Invention).

Following the requirements of the Utility Guidelines (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for Utility.), the first inquiry is whether a credible utility is cited in the specification for use of these nucleic acids. Cited utilities identified by the examiner include immunoregulatory functions such as regulation of the immune system in autoimmune or inflammatory disease. These utilities are credible.

Upon identification of credible utilities, the next issue is whether there are any well-established utilities for the protein. No well established utilities for BMOG or variants thereof are identified in either the specification or in the cited prior art.

Given the absence of a well-established utility, the final issue is whether substantial and specific utilities are disclosed in the specification. Here, no substantial utilities that are specific to BMOG are identified.

As noted in the utility guidelines, methods of treating unspecified diseases, basic research on a product to identify properties, intermediate products which themselves lack substantial utility are all insubstantial utilities. No substantial utility is identified for BMOG (or any BMOG variant) in the specification, only speculative utilities that lack any basis are provided. Further, none of the recited utilities in the specification are specific to BMOG polypeptide, and none rely on any unique feature of BMOG.

Finally, with regard to the utility analysis, the current situation directly tracks Examples 4 and 12 of the utility guidelines, where a protein of entirely unknown function was characterized as lacking utility. In particular, example 12 states that a receptor does not have utility since no "real world" use is identified, just as in the current situation. Further experimentation is

necessary to attribute a utility to the claimed polypeptides. (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for Utility.) Thus, the present disclosure is only a starting point for further research and investigation into potential practical uses of the claimed polypeptides. See Brenner v. Manson, 148 U.S.P.Q. 689 (Sus. Ct, 1966), wherein the court held:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

Claims 1-7 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial and specific asserted utility or, alternatively, a well established utility, one skilled in the art clearly would not know how to use the claimed invention.

New Rejections (necessitated by amendment)

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 has been amended such that it now encompasses DNA sequences which are at least 95% homologous to a **DNA sequence selected from the group consisting of SEQ ID NO: 4, SEQ ID NO: 5, or SEQ ID NO: 6.** (Emphasis added). However, SEQ ID NO: 4, SEQ ID NO: 5 and SEQ ID NO: 6 are amino acid sequences, not DNA sequences. Since claim 3 explicitly claims DNA sequences which are not DNA sequences, the claim is indefinite. It is noted that amending the claim such that it reads on DNA sequences which encode polypeptide sequences which are at least 95% identical to SEQ ID NO: 4, SEQ ID NO: 5 or SEQ ID NO: 6 (and with the same function), would obviate this rejection. Claim 7 is also included in the rejection because claim 7 depends on claim 3.

Claims 4 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 has been amended such that it now reads on the DNA molecule of claim 2 further characterized by encoding a polypeptide with the immunological activity of BMOG, wherein one or more amino acids of said amino acid sequence are substituted, deleted or inserted. It is noted that claim 2 is explicitly limited to an isolated DNA molecule coding for an amino acid sequence comprising SEQ ID NO: 4, SEQ ID NO: 5 or SEQ ID NO: 6. Accordingly, claim 2 does not encompass any variants of SEQ ID NO: 4, SEQ ID NO: 5 or SEQ ID NO: 6.

Since claim 4 depends on claim 2, claim 4 must encompass all of the limitations of claim 2. As such, claim 4 must be limited to an isolated DNA molecule coding for an amino acid sequence comprising SEQ ID NO: 4, SEQ ID NO: 5 or SEQ ID NO: 6. However, claim 4 specifically indicates that the DNA encodes a polypeptide that has one or more amino acids substituted, inserted or deleted. Therefore, claim 4 is drawn to embodiments that do not falls within the scope of claim 2. Accordingly, claim 4 is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Claim 7 is also rejected because claim 7 depends on claim 4.

Response to Arguments

Applicant's arguments filed 8/23/2006 have been fully considered.

With respect to the rejection of instant claims 1-7 under 35 U.S.C. §§ 101/112 1st paragraph, Applicants argue that the specification as filed discloses several credible specific and substantial utilities for the claimed sequences including: (1) activation or blockage of immunoregulatory events by coupling to other proteins such as an immunoglobulin Fc domain to confer favorable properties such as a long serum half life, or (2) blockage of interaction between cell surface BMOG and a receptor protein (i.e., to identify a novel BMOG receptor). Applicants also argue that the specification discloses that (1) BMOG can be used as a diagnostic marker for BMOG in disease states, (2) BMOG polypeptides can be used to raise BMOG-specific antibodies which can be useful for blocking immunological responses or may be incorporated into diagnostic tests.

Applicant's arguments are not persuasive because these asserted utilities do not constitute specific utilities as they are utilities that are applicable to any gene sequence that may have immunoregulatory functions. That is, any gene sequence involved in immunoregulatory function could be used in the following manners: to activate or block immunoregulatory events by coupling to other proteins; to block interaction between the gene sequence and a receptor protein (i.e., to identify a novel receptor for the gene sequence); as a diagnostic marker for the gene sequence in disease states; and to raise antibodies which are specific for the sequence. Therefore, these asserted utilities do not constitute specific utilities.

Furthermore, methods of treating or diagnosing unspecified diseases are insubstantial utilities because further experimentation would be required in order to determine which specific diseases BMOG was involved in before BMOG sequences could be used as diagnostic markers for the disease or as a therapeutic treatment of the disease. Therefore, the present disclosure is only a starting point for further research and investigation into potential practical uses of the claimed polypeptides. Thus, further experimentation is necessary to attribute a specific and substantial utility to the claimed BMOG sequences. (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for Utility.)

Applicants also argue that the specification discloses that experimental evidence establishes that BMOG transcripts are relatively limited to germinal center B cells, indicating a role for BMOG in immunological function.

In response, the expression of BMOG transcripts in spleen, PBLs, lymph nodes, thymus and appendix (as indicated on page 6 of the specification), may lend credence to the assertion

that BMOG sequences are involved in immunoregulatory events as these tissues are recognized as tissues where such events can occur. However, this still does not indicate a specific and substantial utility for BMOG sequences as further experimentation would still be required in order to determine what function BMOG has in these tissues.

Applicants refer to three post-filing references to support their argument that the claimed BMOG sequences can be useful as diagnostic markers for or as therapeutic treatment of immune-based disease (Pende et al., J. Exp. Med. 1999; Ferlazzo et al. J. Exp. Med., 2002; and, Moretta et al. Nat. Immunol., 2002). Applicants indicate that the three indicated post-filing references were submitted as Exhibits A, B and C.

In response, it is pointed out that the communication filed 8/23/2006 did not include the three post-filing references which applicants cite (Pende et al., Ferlazzo et al. and Moretta et al.) That is, no appendix was attached to Applicants response. Therefore, the indicated references cannot (and have not) been considered by the Examiner. Should applicants wish to have the reference considered, they should submit the references in their entirety. However, even without copies of the cited references, applicants arguments presented with respect to the cited references are not persuasive. Applicants argue that Pende et al. confirm that BMOG is a receptor expressed on natural killer cells and that BMOG induces the cells to become cytotoxic. Applicants argue that Ferlazzo et al. NK cells are activated by dendritic cells via BMOG.

However, the specification appears to base all of the asserted utilities on the assertion that BMOG transcripts are expressed in tissues where immunoregulatory events are known to occur (e.g., locations germinal center B cells). However, merely identifying the location of BMOG

transcription does not indicate any specific or substantial use for BMOG sequences. Certainly further experimentation would be required in order to discern the function of BMOG in these tissues. With respect to the asserted teachings of Pende et al., the specification does not indicate that BMOG is expressed on natural killer cells or that BMOG induces cytotoxicity in cells. With respect to the asserted teachings of Ferlazzo et al., the specification does not indicate that BMOG is dendritic cells activate NK cells via BMOG. Therefore, Pende et al. and Ferlazzo et al. teach significantly more than that which is disclosed in the specification. That is, the specification is not commensurate with the teachings of Pende et al. and Ferlazzo et al.

Applicants also assert that Moretta et al. teaches that NK cells are important members of the immune response and are involved in the control of tumor growth, viral and microbial defense, autoimmunity and transplant rejection.

In response, the Examiner does not take issue with the assertion that NK cells are important members of the immune response involved in the indicated processes. It is respectfully pointed out, however, that there is no assertion that Moretta et al. in any way indicates anything specific about BMOG. Therefore, the asserted teaching of Moretta et al. does not support applicant's contention that the specification provides patentable utility for the claimed BMOG sequences.

Accordingly, based on the disclosure of the specification, one skilled in the art would be required to carry out further research to identify or reasonably confirm a "real world" context of use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. Thus, the present disclosure is only a starting point for further research and investigation into potential practical uses of the

claimed nucleic acid sequences. See Brenner v. Manson, 148 U.S.P.Q. 689 (Sus. Ct, 1966), wherein the court held:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

Therefore, Applicants arguments are not persuasive.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on 9:00 a.m.- 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.